

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PENN-0690	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/15308	International filing date (day/month/year) 07 JULY 1999	Priority date (day/month/year) 07 JULY 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00, 38/16; C07K 14/00 and US Cl.: 514/2,13 ; 530/300, 326		
Applicant THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of 0 sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

CORRECTED
VERSION

Date of submission of the demand 01 FEBRUARY 2000	Date of completion of this report 24 SEPTEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer BENNETT CELSA TERRY J. DEY PARALEGAL SPECIALIST TECHNOLOGY CENTER 1600
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/15308

I. Basis of the report

1. With regard to the elements of the international application: *

☒ the international application as originally filed

☒ the description:

pages 1-20

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of

☒ the claims:

pages 21-23

pages NONE, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of

☒ the drawings:

pages NONE

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of

☒ the sequence listing part of the description:

pages 1

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig. NONE

5. ☒ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 2-6 and 9-14

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination (*specify*).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _ are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 2-6 and 9-14.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)

Claims	<u>1 and 8</u>	YES
Claims	<u>7</u>	NO

Inventive Step (IS)

Claims	<u>1 and 8</u>	YES
Claims	<u>7</u>	NO

Industrial Applicability (IA)

Claims	<u>1, 7 and 8</u>	YES
Claims	<u>NONE</u>	NO

2. citations and explanations (Rule 70.7)

Claim 7 lacks novelty under PCT Article 33(2) as being anticipated by Hider et al. This reference discloses tertipin and a family or related peptides which share the same alpha helical structure (e.g. see page 197) and compositions comprising these peptides which are taught by the reference to possess therapeutic utility which anticipates pharmaceutical compositions or alternative renders the formation of such composition obvious (e.g see page 202 and page 207).

Applicant's arguments in the "Response to Written Opinion" (paper no. 13) are hereby acknowledged.

Applicant arguments directed to the above lack of novelty of claim 7 over the Hider et al. reference were considered but deemed nonpersuasive for the following reasons.

Applicant argues that the Hider et al. reference fails to disclose or suggest the making of a pharmaceutical composition of a "tertipein-like alpha helix" compound.

This is not found persuasive since both the alpha helical nature of the reference peptides shared with tertipin is taught by the reference (e.g. see page 197 and page 206) as well as the reference peptides possession of pharmaceutical properties e.g. "bee venom peptides" at page 296; and more importantly "... reasons for the marked differences in *pharmacological properties* ..." at page 207 (emphasis provided).

Claims 1 and 8 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed invention (e.g. the modified tertipin peptide comprising seq. id 2).

Claims 1, 7 and 8 meet the criteria set out in PCT Article 33(4).

----- NEW CITATIONS -----

NONE

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE